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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/057,943

01/29/2002

Henry Wolfe

WOLF3002/REF/C

4872

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7590

09/02/2004

AMERSHAM HEALTH  
IP DEPARTMENT  
101 CARNEGIE CENTER  
PRINCETON, NJ 08540-6231

EXAMINER

HARTLEY, MICHAEL G

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 09/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

849

## Office Action Summary

Application No.

10/057,943

Applicant(s)

WOLFE ET AL.

Examiner

Michael G. Hartley

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-21, 26, 28, 29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-21, 26, 28, 29 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/2004 has been entered.

***Response to Amendment***

The amendment filed 6/21/2004 has been entered.

***Response to Arguments***

Claim 28 is rejected under 35 U.S.C. 102(e) as being anticipated by Tomalia (US 5,714,166), as set forth in the last office action.

Applicant's arguments filed 6/21/2004 have been fully considered but they are not persuasive.

Applicant asserts that amended claim 1 includes the limitation that the targeting agent comprises E. coli heat stable enterotoxin STa, which is not disclosed by Tomalia.

This is not found persuasive for claim 28, as this claim is neither dependent upon claim 1 nor contains the limitation asserted as being distinguishable from Tomalia.

Applicant's arguments with respect to claims 1-6, 8-21, 26, 28, 29 and 31 have been considered but are moot in view of the following new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

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obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-21, 26, 28, 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomalia (US 5,714,166) in view of Waldman (US 5,518,888).

Tomalia discloses a compound comprising a radially asymmetric dendrimeric polymer (e.g., a dendrimer), linked to at least one reporter, which comprises a plurality of amino acids, as discussed above. Tomalia teaches that various reporters and/or amino acids may be used interchangeably, as equivalents, in the compounds to yield useful imaging agents for a variety of imaging modalities, see column 18 and claims 65 and 66. Tomalia teaches that basically any useful targeting director may be used including various proteins, antibodies, etc., to provide the advantage of targeting the dendrimers to a specific site in vivo, see columns 22-26.

Tomalia fails to specifically disclose that the targeting director is an E. coli heat stable enterotoxin STa, a claimed.

Waldman teaches that it is known in the art to conjugate diagnostic and/or therapeutic compounds to E. coli heat stable enterotoxin STa to provide the advantage specifically targeting metastasized colorectal cancer in vivo, e.g., for radioimaging, etc. see abstract and columns 3-4.

It would have been obvious to one of ordinary skill in the art to use to use to E. coli heat stable enterotoxin STa as the targeting agent in the compounds and methods disclosed by Tomalia because it is known in the art that this enterotoxin is a useful targeting moiety for diagnostic and therapeutic compounds to provide the advantage specifically targeting metastasized colorectal cancer in vivo, as shown by Waldman, while Tomalia teaches that any useful targeting moiety may be employed to target a desired site. Thus, One of ordinary skill in the art would be motivated to use to E. coli heat stable enterotoxin STa in the invention of Tomalia to obtain diagnostic and therapeutic agents that are specifically useful for metastasized colorectal cancer, as taught by Waldman.

### ***Conclusion***

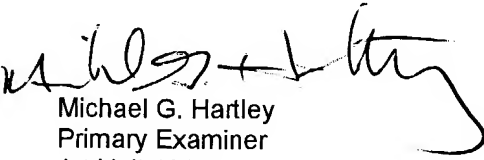
No claims are allowed at this time.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael G. Hartley  
Primary Examiner  
Art Unit 1616

8/31/2004